REMARKS

Claims 2-4, 8, 10, 14, 24, 25, 35, 37, and 52-54 have been amended. Claims 59-61 have been added. Claims 1 and 15-20, 22, and 23 have been cancelled. Claims 6, 9, 11-13, 21, 26-34, 40-42, 47, and 49-51 were cancelled in a previous Response(s). Accordingly, claims 2-5, 7, 8, 10, 14, 24, 25, 35-39, 43-46, 48, and 52-61 are now presented for the Examiner's review and consideration. Applicants believe the claim amendments, cancellations, and additions and the accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

Amendments to the Claims

It is noted that the references to the application/specification made in this Response are meant only to represent examples of support for amendments and/or teachings of the application/specification (used in response to claim rejections) and are not and should not be interpreted as a comprehensive list of support. The amendments and/or referenced subject matter may be supported in other parts of the application/specification not referenced.

No new matter has been added by the amendments to claims 2-4, 8, 10, 14, 24, 25, 35, 37, and 52-54 made herein. These claims have been amended in light of the addition of new claims 59-61 and/or to provide proper antecedent basis for all terms recited therein.

No new matter has been added with the addition of claims 59-61 made herein.

New independent claim 59 is directed to a surgical device for securing tissue and incorporates subject matter of cancelled claim 1. Generally, the device includes, *inter alia*, a first member, a second member having an elongated insulation sleeve, and an energy source. The second member is movable with respect to the first member from a first position to a second position. The first member is configured to contact a retainer in the second position. The energy source is operably connected to the first member and functions to apply energy to the retainer. The elongate insulation sleeve of the second member is positionable to control application of energy from the energy source. This surgical device is both described and illustrated in the

specification as originally filed. *See* paragraphs **[0036]**; **[0037]**; **[0060]**; **[0064]-[0067]**; **[0371]-[0385]**; and **[0519]-[0542]**; and Figures 25, 25A, 48, and 52-55 of the published application, U.S. Patent Application Publication 2004/0230223 A1; hereinafter "published application."

New dependent claim 60 clarifies that the first and second members of the surgical device are spaced such that a retainer may be received therebetween when in the second position and are configured (the first and second members) to apply compressive force to the retainer when in the first position. These characteristics of the first and second members are both described and illustrated in the specification as originally filed. *See* paragraphs **[0066]**; **[0067]**; and **[0538]** and Figures 54, 55 of the published application.

New dependent claim 61 clarifies that the second member of the surgical device has a body and that the elongated insulation sleeve moves independently of the movement of the body (of the second member). This structure and movement is described in the specification as originally filed. *See* paragraphs **[0537]-[0542]** of the published application.

Rejections under 35 U.S.C. §103(a)

Claims 1-5, 7, 8, 10, 14-20, 22-25, 35-39, 42-46, and 48 were rejected under 35 USC §103(a) as allegedly being unpatentable over Winston et al. (U.S. Patent 3,513,848; hereinafter "Winston") in view of InBae Yoon (U.S. Patent 5,908,429; hereinafter "Yoon"). Claims 52-58 were rejected under 35 U.S.C. §103(a) as being unpatentable over Winston in view of Yoon and further in view of James S. Bates et al. (U.S. Patent 6,348,056 B1; hereinafter "Bates").

For reasons set forth below, Applicants respectfully submit that these rejections should be withdrawn.

It is noted that the references are described individually only to clarify what each reference teaches. Thus, the separate description of references presented herein is not and should not be interpreted as an attempt at arguing each reference separately.

Winston

Winston discloses an apparatus and a method for forming sutures using ultrasonic vibrational energy. The ultrasonic energy can be applied to either overlapping portions of a suture without the use of a knot or it (the ultrasonic energy) can be applied to a knot in the suture. *See* abstract. The apparatus is illustrated in Figures 3, 3A, and 11. This apparatus includes vibrator means **45a** in the form of a hand held instrument, including an ultrasonic transducer or motor **65a** for effecting the high frequency vibrations of the tool member **55a**. The tool member **55a** has an enlarged portion **57a** terminating in a work surface **56a** and a base **66a** secured to insert portion **67a**. The apparatus further includes support means **46a** that acts as an anvil or clamp, so that overlapping layers of suture thread **39a** and **40a** may be compressed between working surface **56a** and a support surface **49a** provided on the vibratory and support means. *See* column 10, lines 3-19. The support means **46a** can include a pair of legs **74a** and **75a** secured together at their lower end by bands **76a** and provided with finger gripping means in the form of individual lugs **77a** that extend outwardly from the upper end of the legs for engagement by fingers of the surgeon or operator **68a**. *See* column 10, line 73 to column 11, line 6. The legs **74a** and **75a** are spaced in relation to each other and can be contoured to conform to the cylindrical configuration of the ultrasonic transducer housing **70a**. The apparatus and method of Winston help to eliminate the loosening of a suture after its formation, and thus maintain tension in the sutures. *See* abstract and column 3, lines 51-53.

Yoon

Yoon discloses methods of anatomical tissue ligation and an apparatus for carrying out the methods. Specifically, Yoon discloses the steps of introducing a distal end of a single anatomical tissue ligation instrument assembly at an internal operative site in a patient's body, grasping anatomical tissue at the internal operative site with a grasping member of the anatomical tissue ligation instrument assembly disposed at the distal end, positioning a contractible ligature loop formed of a length of filamentous ligature material of the anatomical tissue ligation instrument assembly around the anatomical tissue while the anatomical tissue remains grasped by the grasping member external of the distal end, contracting the ligature loop

around the anatomical tissue to form a ligature and severing the length of ligature material proximally of the ligature to separate the ligature from the remainder of the length of ligature material. *See* Abstract and column 2, line 66 to column 3, line 21.

In an embodiment of the method, Yoon discloses that a grasping instrument **16** can be designed to supply energy to anatomical tissue to treat the tissue. For example, grasping instrument **16** can be provided with an electrical connector **61** coupled with inner member **38**, in which case the inner member **38** and grasping members **50A** and **50B** are made of electrically conductive material. Electrical connector **61** is adapted to be connected with a source of electric current for transmission of electricity via the inner member **38** to treat anatomical tissue contacted by grasping members **50A** and **50B**, such as for electrical cautery or coagulation. Where the inner member **38** is designed to transmit electricity, it is preferable that the outer member **36** be made of electrically insulative material. As shown in FIG. 5 (Yoon), the outer member has an additional longitudinal slot **37** through which connector **61** extends, the slot **37** permitting longitudinal movement of the outer member **36** and/or the inner member **38** relative to the other since the connector **61** is slidable along the slot **37**. In addition, it is desirable that the grasping instrument **16** be longitudinally movable relative to barrel **12** such that the distal end of the grasping instrument can be retracted or drawn into the barrel for safety and protection, and it is preferable that the barrel be made of electrically insulative material. *See* column 8, lines 34-57.

Yoon exemplifies this embodiment (application of energy to tissue) through cauterization of tissue after the ligation procedure. For example, FIG. 15 illustrates the grasping members **50A** and **50B** grasping the stump of tissue structure T therebetween with electricity being supplied to the stump via the tips **54A** and **54B** of the grasping members **50A** and **50B** for electric cautery to control bleeding. *See* column 4, lines 14-16; column 15, lines 30-36; and Figure 15. Additionally, Figure 24 illustrates cautery of the ends of a blood vessel. *See* column 4, lines 47-48; column 18, lines 20-30; and Figure 24.

Bates

Bates discloses medical instruments (and methods for using the instruments) for capture and/or release of materials within the body, for example gall stones and urinary tract stones. *See* abstract; column 1, lines 5-10; and column 3, line 26-column 4, line 13. The instrument is designed such that it can capture and release material while the instrument is still positioned within the body. *See* column 2, lines 2-6.

The embodiment cited in item 8 of the final Office Action mailed on May 14, 2010 is shown in Figures 11*a* and 11*b*. A sheath **12** adjacent the handle includes a slot **14**. The sheath **12** is operably attached to a pin **18** movable in a slot **14**. When the pin **18** moves in the slot **14** from the distal position shown in FIG. 11a to the proximal position shown in FIG. 11b, the sheath **12** also moves in the proximal direction as shown in FIG. 11b. As the sheath **12** moves proximally, the proximal portion **22** of the retrieval assembly expands as it is uncovered by the distal sheath end **15**. *See* column 10, line 61-column 11, line 2.

Instant Invention

The instant invention, as currently claimed in independent claims 24, 25, 35, 43, 44, 48, and 59, provides a surgical device for securing tissue. Generally, the claimed surgical device of each independent claim includes, *inter alia*, a first member, a second member, an elongated insulation sleeve, and an energy source. The second member is movable with respect to the first member from a first position to a second position. The energy source is operably-connected to the first member and applies energy. The elongated insulation sleeve of the second member is positionable to control application of energy from the energy source. *See* paragraphs **[0036]**; **[0037]**; **[0060]**; **[0064]-[0067]**; **[0371]-[0385]**; and **[0519]-[0542]**; and Figures 25, 25A, 48, and 52-55 of the published application.

Argument

As an initial matter, Applicants respectfully request that the rejections based on obviousness be re-assessed in light of the USPTO publication of "Examination Guidelines Update: Developments in the Obviousness Inquiry After KSR v. Teleflex," **Fed Reg.** 75, pp53643-659 (Sept

1, 2010).

Applicants respectfully submit that the invention, as claimed herein, is not obviated by the combination of Winston and Yoon, with or without the addition Bates.

First, the claimed surgical device can not be derived from the cited patents (Winston and Yoon or Winston, Yoon, and Bates) since all elements (of the surgical device) are not found in the combined teachings (of the cited patents).

As noted above, the surgical device of independent claims 24, 25, 35, 43, 44, 48, and 59 includes, *inter alia*, an elongated insulation sleeve. This sleeve is controllably positionable over the second member to limit application of energy from the energy source. The movement or "controlled positionability" of the elongated insulation sleeve is independent of the movement of the second member. The prior art does not disclose such a device.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Therefore, in order for an Examiner to properly establish a *prima facie* case of obviousness, the Examiner first must show that all the elements of the claimed invention are known or suggested in the prior art.

In the instant case, the rejections are based on the Examiner's assertion that Yoon discloses an elongated insulation sleeve that can be added to/combined with Winston's device to produce the claimed surgical device.

In item 7, at page 4, of the final Office Action mailed on May 14, 2010, the Examiner states

*"Yoon teaches of a surgical device comprising an instrument designed to transmit various forms of energy controllably positioned into an insulated sleeve **12**."*

Applicants agree that Yoon teaches a device including an instrument controllably positioned within an insulated sleeve, however, such a statement has little relevance to the instant invention, as in the claimed surgical device, the elongated insulation sleeve itself is movable/controllably positionable rather than any other part of the device. *See* paragraphs **[0537]** and **[0538]** of the published application.

As established in the previous Response, the distinctions between Yoon's device and the claimed device are easily surmised. Yoon discloses an electrically-insulated barrel **12**, however, in

the instant case, the fact that two tubular elements are insulated is insufficient to render them (two tubular elements) equivalent. Further, as described by Yoon, a tissue-grasping instrument **16** is disposed within barrel **12** and can be designed to supply energy to tissue. The tissue-grasping instrument **16** is longitudinally movable with regard to barrel **12** such that the distal end of the instrument can be retracted or drawn into the interior of the barrel **12**, *i.e.* the tissue-grasping instrument **16** slides within barrel **12**, barrel **12** does not slide over the tissue-grasping instrument **16**. Thus, barrel **12** is stationary with respect to other elements of Yoon's device and can not be controllably positionable or even capable of independent movement. *See* column 5, lines 41-48; column 8, lines 34-59; and Figures 1, 2, and 5. Additionally, Yoon discloses sleeves **28A**, **28B**, and **28C** disposed within and fixedly secured to barrel **12**. *See* column 5, line 65-column 6, line 18. Since neither the barrel nor sleeves disclosed by Yoon are structured for independent movement, they (the barrel and sleeves of Yoon) can not be considered akin to the elongated insulation sleeve of the claimed surgical device. Likewise, since the structure (of the barrel and sleeves of Yoon's device) is stationary, it follows that the movement/controllable positionability (*i.e.* function) of the elongated insulation sleeve of the claimed device is impossible to achieve using either the barrel or sleeves of Yoon.

Thus, it is clear from the above discussions that the combined teachings of Winston and Yoon lack all of the elements of the surgical device as currently claimed. Therefore, in contrast to the Examiner's conclusion, merely surrounding the device of Winston with the barrel or sleeves of Yoon would not produce the surgical device of the claimed invention. Accordingly, Applicants respectfully submit that the Examiner has failed to provide a convincing showing that all elements of the device, as currently claimed, are taught/disclosed by the cited patents.

Even if the cited patents (Winston and Yoon) were combinable to produce the claimed surgical device, a simple teaching of elements is insufficient. In order to establish a proper *prima facie* case of obviousness, the prior art must also suggest the desirability of the claimed invention and/or give some reason or motivation for the cited art to be combined.

Obviousness can be established by combining or modifying teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so. In

re Kahn, 441 F.3d 977, 986, 78 USPQ2d 1329, 1335 (Fed. Cir. 2006); see MPEP 2143.01 I.

"The question under 35 USC 103 is not merely what the references expressly teach but what they would have suggested to one of ordinary skill in the art at the time the invention was made." In re Lamberti, 545 F.2d at 750, 192 USPQ at 280 CCPA 1976.

Applicants respectfully submit that even if the references did disclose all of the elements of the currently-claimed surgical device, one of ordinary skill in the art would not have combined the teachings of the cited patents (Winston and Yoon) because there is no motivation to do so.

The Examiner asserts "*Given the teachings of Yoon, it would have been obvious to have provided Winston with such a sleeve, in order to protect the user and the patient from possible burns, while providing a sleeve through which the device could be inserted in order to suture internally.*"

First, Yoon teaches direct application of energy to tissue for cautery to control bleeding. *See* column 15, lines 29-35 and Figure 15. If one is carrying out direct application of energy to tissue, one would not be using a sleeve or any other protective measure to prevent energy from reaching the tissue. Thus, Yoon is not suggestive of the necessity or desire for protective sleeves.

Winston discloses that the support means **46b** or vibratory means **45b** may be placed in engagement with the biological organism **20b** without causing any damage thereto. Emphasis added herein by Applicants. *See* column 12, lines 41-46. Thus, Winston specifically teaches that tissue could be directly contacted by his device without adverse effect. If one could use the device without worrying about harming the tissue, why would one think of using a protective sleeve? Accordingly, Winston actually teaches away from the combination by suggesting that a protective sleeve is not necessary for his device. A showing of "teaching away" supports an argument for nonobviousness.

A claimed combination of prior art elements may be nonobvious where the prior art teaches away from the claimed combination. Crocs, Inc. v. U.S. Int'l Trade Comm'n. 598 F.3d 1294 (Fed. Cir. 2010).

Considering the above, one of ordinary skill in the art would not find any reason for combining the teachings of Winston and Yoon. Thus, Applicants respectfully submit that the Examiner has not only failed to show that all elements of the claimed invention are known or suggested in the art, the Examiner has also failed to show that one of ordinary skill in the art would have some reason or motivation to put all the elements together to achieve the claimed invention even if all the elements were known. Accordingly, a proper *prima facie* case has not been established.

As noted above, the surgical device of independent claims 24, 25, 35, 43, 44, 48, and 59 includes, *inter alia*, an elongated insulation sleeve. This sleeve is controllably positionable over the second member to limit application of energy from the energy source. The movement or "controlled positionability" of the elongated insulation sleeve is independent of the movement of the second member.

Based upon all of the above arguments, it is clear that the combination of Winston and Yoon does not teach a surgical device having an elongated insulation sleeve as claimed. Furthermore, considering that devices for securing tissue or applying energy to tissue are absent from the disclosure of Bates, the addition of Bates as a secondary reference does nothing to remedy the deficiencies of the combined teachings of Winston and Yoon. Thus, even if one of ordinary skill in the art were to combine the teachings of Winston, Yoon, and Bates, the currently-claimed surgical device would not be the result.

Response to Arguments

In reply to the Response to Arguments (items 2-4) in the Final Office Action, Applicants offer the following.

The characterization of the "movement/positionability of the sleeve of the currently-claimed device" as an intended use is incorrect. The movement or sliding of the sleeve is not merely an intended use; rather it is a recitation that results from the structure of the as-claimed device.

The invention, as currently claimed, provides a surgical device for securing tissue, the device including an elongated insulation sleeve that is controllably positionable over a second member, a tubular member, and/or a force-transmitting member. The positionability of the

elongated insulation sleeve limits application of energy to a retainer and/or the gapped portion of the device. Likewise, when the retainer is used with a suture, the suture is shielded from the energy. Additionally, when the device is in use the surrounding tissue is protected from potentially-damaging contact with the energy. The configuration, *i.e.* structure, of the surgical device allows the elongated insulation sleeve to slide over the tubular/second member. If the surgical device did not have this configuration, the elongated insulation sleeve would not be capable of controlled positionability. Thus, the movement/positionability is not merely an intended use.

Even assuming *arguendo* that "movement/positionability of the sleeve of the currently-claimed device" is an intended use, Winston in view of Yoon is not capable of performing the movement/positionability. With Yoon, the instrument slides within a stationary sleeve. As noted above, in the claimed invention, the insulation sleeve is not stationary, but rather slides over the second/tubular member. As described by Yoon, a tissue-grasping instrument **16** is longitudinally movable with regard to barrel **12** such that the distal end of the grasping instrument can be retracted or drawn into the barrel, *i.e.* the tissue-grasping instrument **16** slides within barrel **12** and barrel **12** does not slide over the tissue-grasping instrument **16**. Thus, the barrel **12** is stationary with respect to other elements of the device. *See* column 8, lines 34-59; and Figures 1, 2, and 5. Thus, with Yoon, it is the instrument that moves and not the barrel. Furthermore, Yoon discloses sleeves **28A**, **28B**, and **28C** disposed within and fixedly secured to barrel **12**. *See* column 5, line 65-column 6, line 18. As a result, the movement/positionability of the sleeve of the currently-claimed device is impossible to achieve using the either the barrel or the sleeves of Yoon's device with Winston's device.

Applicants respectfully disagree with the contention that "protecting the unintentional tissue damage should be consistent with both devices" of Winston and Yoon. As noted above, Yoon teaches direct application of energy to tissue and Winston teaches that his device can contact tissue without causing damage. Thus, neither device is consistent with "protecting unintentional tissue damage."

The issue of "motivation to combine" the references is addressed in detail above.

Accordingly, based upon all of the above, Applicants submit that independent claims 24, 25, 35, 43, 44, 48, and 59 are patentable over Winston in view of Yoon and Winston in view of Yoon and further in view of Bates. As claim 53 depends from claim 24; claim 54 depends from claim 25; claims 36-39, 45, 46, and 55 depend from claim 35; claim 56 depends from claim 43; claim 57 depends from claim 44; claim 58 depends from claim 48; and claims 2-5, 7, 8, 10, 14, 52, 60, and 61 depend from claim 59, these dependent claims necessarily include all the elements of their respective base claims. Thus, Applicants respectfully submit that these dependent claims are allowable over Winston in view of Yoon and Winston in view of Yoon and further in view of Bates at least for the same reasons.

In light of all of the foregoing arguments, Applicants respectfully request reconsideration and withdrawal of the rejections of claims under 35 U.S.C. §103(a).

Conclusion

In light of the foregoing amendments and remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this Response or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

The fee for a three month extension of time pursuant to 37 C.F.R. § 1.17(a)(3) in the amount of $555 and the fee for a request for continued examination pursuant to 37 C.F.R. § 1.17(e) in the amount of $405 are believed to be due and are being paid via credit card. No other fees are believed to be due at this time. However, please charge any other required fee (or credit overpayments) to the Deposit Account of the undersigned, Account No. 503410 (Docket No. 782-A03-024).

Respectfully submitted,

/Paul D. Bianco/

Paul D. Bianco, Reg. # 43,500
Customer Number: 33771
FLEIT GIBBONS GUTMAN BONGINI & BIANCO P.L.
21355 East Dixie Highway, Suite 115
Miami, Florida 33180
Tel: 305-830-2600; Fax: 305-830-2605
e-mail: pbianco@fggbb.com